REMARKS

In the Office Action, the Examiner states that the Information Disclosure Statement does not comply with the requirements of 37 C.F.R. 1.98. In a telephone inquiry to the Examiner on July 10, 2003, the Examiner said that the references were located. In the telephone conversation, the Examiner indicated that the references would be reviewed and the PTO Form 1449's initialed. A supplemental information disclosure statement also accompanies this amendment.

With respect to the objection to the drawings under 37 C.F. R. 1.83 (a), Figure 4 has been amended as shown in red on the attached sheet to illustrate the wire 22' with J-tip 24' extending from the catheter to better illustrate the wire within the catheter. A copy of the drawing incorporating the changes is also enclosed. No new matter has been added. The specification makes clear that the wire extends from the catheter. See e.g. page 6 lines 15-19 stating "A rotatable thrombectomy wire 22 preferably having a J-shaped tip designated generally 24 is slidably resident within major internal conduit 14. Wire 22 may be advanced out of a distal end 32 of major internal conduit 14 within catheter 12 to perform thrombectomy procedures....". Withdrawal of the objection to the drawings in light of the foregoing is respectfully requested.

With respect to the rejection of claim 1 under 35 U.S.C. 112, second paragraph, claim 1 has been amended to reference the guide wire. The rejection should be withdrawn.

Claims 1-4, 6-8, 10-12, 17, 20, 24, and 25 were rejected as obvious over U.S. Patent No. 6,056,721 (Schulze) in view of U.S. Patent No. 6,183,487 (Barry).

The Schulze patent is directed to a combination angioplasty and drug delivery catheter. The patent, as explained by Schulze, is an improvement over prior angioplasty and drug delivery catheters, stating in his Background of the Invention that there is a need for "a combination angioplasty drug delivery catheter of a less complex design" and "for a balloon catheter which allows efficient autoperfusion without substantially increasing the diameter of the deflated catheter device" and for a catheter device "capable of adequate drug volume delivery between the balloons.

As explained in Schulze's specification, the drug is injected in the region between the two inflated balloons, i.e. the sealed space between balloon 46 and balloon 50. Schulze explains:

> *The present invention also satisfies the need for a balloon catheter device which can perform angioplasty procedures and deliver high volumes of therapeutic drugs within a body passageway... (col. 3, lines 11-13.)*

The high compliance balloon 46 may be inflated to anchor the catheter device 10 within the body passageway 12 as well as to prevent a fluid 76, such as blood or any other body fluid from moving beyond the balloon 46. (col. 11, lines 14-19)

This allows the drug 44 to exit the infusion port 40 into the sealed space between the high compliance balloon 46 and the angioplasty balloon 50. (col. 11, lines 27-31)

As can be appreciated, Schulze's only teaching is for fluid delivery to clear the obstruction. Further the balloons are necessary to contain the fluid. Schulze's device requires the treatment fluid to be injected between the balloons.

The Examiner contends that it would have been obvious to substitute Barry's guidewire 225 for the guidewire in Schulze. Applicants submit that this reasoning is flawed for several reasons. Additionally, the amendments to the claims further overcome the obviousness rejection.

First, there is no teaching or suggestion to modify the Shulze device to provide a mechanical obstruction treatment device. The sole objective and disclosure of Schulze is an enhancement of fluid delivery, not mechanical contact to clear the obstruction. In the absence of such suggestion, such modification is impermissible hindsight reconstruction. As explained in the MPEP, section 2143.01, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination" (citing *In re Mills*, 916 F2d. 680, 16 USPQ 2d 1430 (Fed. Cir. 1990). The MPEP continues, "Although a prior art device may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so..." In the present combination of references, not only is there no suggestion to combine, but the desirability and motivation is lacking. There is no motivation to modify a fluid delivery device to substitute a rotatable mechanical wire.

Second, such modification is against the teachings of Schulze. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d. 810, 123 USPQ349 (CCPA 1959); MPEP section 2143.01. A mechanical wire would change the teachings of Shulze. The objective of Schulze is to improve fluid injection. Further, placement of a mechanical wire distal of both balloons, as recited in the claims of the present application, goes against the teachings of Schulze, which requires the obstruction

treatment occur between the balloons in a confined space. Changing the location of the Schulze balloons relative to drug injection runs counter to the teachings and objectives of Schulze. The balloons of Schulze create a space for drug injection; moving the drug injection distal of the balloons would not enclose the drug treatment area but would do the opposite as flow would not be inhibited. Substituting a rotational member for the drug injection is therefore counter to the teachings, objectives, and focus of the Schulze patent. Thus such combination is improper.

Such modification is also contrary to the teachings of Barry. Barry differentiates in his Background of Invention Section drug therapy and mechanical treatment. In modifying a drug treatment device, i.e. Schulze, one of ordinary skill in the art would not look to a patent that wants nothing to do with drug (pharmaceutical treatment) but focuses on mechanical atherectomy.

Third, assuming solely for the sake of argument that the references were combined as the Examiner suggests, the requirements of the claims as amended are not met. Independent claims 1, 10, 11 and 12 all require that the rotational wire rotates to break up thrombus to perform the thrombectomy procedure in an area distal of the first and second balloons. Barry discloses the use of an elliptical atherectomy burr with abrasive material to perform the procedure of breaking up the occlusion, e.g. physically contacting and removing the occluding material. In the embodiment of Figures 16 and 17 of Barry, a rotatable wire is disclosed which is rotatable to "create a path for the burr." Rotation of the burr is still necessary to remove the occluding material. Thus, even assuming arguendo Schulze is modified with the wire of Barry, the wire would not perform the thrombectomy procedure as required, but rather only "create a path for the burr" to perform the atherectomy procedure.

In short, the Examiner suggests modifying Schulze's fluid injection device to provide a rotational wire of Barry to mechanically remove the obstruction. This means that the wire of Barry must be placed distal of the balloons, in a position not contemplated by Schulze and in fact contrary to the teachings of Schulze. This also means that the wire of Barry must be used to remove the obstruction, rather than just provide a path for the solid obstruction removing ablation burr as taught by Barry. Applicants respectfully submit that this combination is improper, and the claims, as amended, are patentable over the prior art. Therefore, applicants respectfully request the withdrawal of the rejection of independent claims 1, 10, 11 and 12.

• Claims 2-4, 6-8, 17, 20, 24 and 25 depend from independent claims 1, 10, 11 or 12 and are therefore believed patentable for at least the same reasons that the independent claims are believed patentable.

Applicants respectfully submit that this application is now in condition for allowance. Prompt and favorable reconsideration of the present application is respectfully requested. The Examiner is invited to contact the undersigned should the Examiner believe it would expedite prosecution.

Respectfully submitted,

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By: _____

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